DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Los Angeles District

19701 Fairchild
Irvine, California 92612-2506
Telephone (949) 608-2900

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

August 3, 2006

W/L 34-06

Ms. Lan Ly, President
Mr. Raymond Ho, Manager
Blue Sea Import Corporation
2890 Ashmont Ave.,
Arcadia, CA 91006-5516

Dear Ms. Ly and Mr. Ho:

We inspected your seafood importer establishment, located at 2890 Ashmont Ave., Arcadia, CA 91006-5516 on June 7, 2006. We found that you have serious violations of the seafood Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR Part 123). The specific requirements for imported fish and fishery products are set out in 21 CFR 123.12. As an importer of fish or fishery products, you must operate in accordance with the requirements of Part 123. In accordance with 21 CFR 123.12(d), there must be evidence that all fish and fishery products offered for entry into the United States have been processed under conditions that comply with 21 CFR Part 123. If assurances do not exist that the imported fish or fishery product has been processed under conditions that are equivalent to those required of domestic processors under 21 CFR Part 123, the fish or fishery products will appear to be adulterated under Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4) and will be denied entry. Because our inspection identified serious violations for 21 CFR Part 123, your Frozen Cooked Apple Snail Meat, Frozen Cooked Baby Clams Meat, Frozen Cooked Anchovy Fish and Frozen Cooked Crab Meat are adulterated under Section 402(a)(4)of the Act (21 U.S.C. § 342(a)(4)), in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You may find the Act, the seafood HACCP regulation and the Fish and Fisheries Products Hazards & Controls Guidance through links in FDA's home page at www.fda.gov.

Your significant violations were as follows:

- You must implement an affirmative step which ensures that the fish and fishery product you import are processed in accordance with the seafood HACCP regulation, to comply with

21CFR 123.12(a)(2)(ii). However, your firm did not perform an affirmative step for Frozen Cooked Apple Snail Meat, Frozen Cooked Baby Clams Meat, Frozen Cooked Anchovy Fish and Frozen Cooked Crab Meat manufactured by [redacted] in [redacted].

We may take further action if you do not promptly correct these violations. For instance, we may take further action to refuse admission of your imported fish or fishery products under Section 801(a) of the Act (21 U.S.C. § 381(a)), including placing them on "detention without physical examination," seize your product(s) and/or enjoin your firm from further violating the Act.

You should respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these violations. You should include in your response documentation, such as HACCP and importer verification records and records that document the performance and results of your firm's affirmative steps, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, you should explain the reason for your delay and state when you will correct any remaining violations.

This letter may not list all the violations at your facility. You are responsible for ensuring that your seafood importer establishment operates in compliance with the Act and the seafood HACCP regulation (21 CFR Part 123). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations for the fish or fishery products that you import into the United States.

Please send your reply to:

Food and Drug Administration,
Attention: J. Lawrence Stevens,
Director, Import Operations Branch
Los Angeles District
222 West 6th Street, Suite 700
San Pedro, CA 90731

If you have questions regarding any issues in this letter, please contact Ruth P. Dixon, Compliance Officer at (310)971-2299.

Sincerely,

Alonza E. Cruse
District Director
Los Angeles District Office

cc: Department of Health Services
Food and Drug Branch
P.O. Box 997413, MS-7602
Sacramento, CA 95899-7413